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## **ISO GUIDE 65 ACCREDITATION FOR ORGANIC CERTIFICATION BODIES**

### **Scope**

The policies and procedures in this document apply when providing service to organic product certification bodies requesting conformity assessment to the International Organization for Standardization (ISO) Guide 65-General requirements for bodies operating product certification systems.

### **Reference Documents**

The following documents are incorporated by reference throughout the instruction:

- ISO Guide 65-Requirements for bodies operating product certification systems
- ISO 10011-1:1990, Guidelines for auditing quality systems-Part 1-Auditing

### **Policy**

The Livestock and Seed (LS) Program, Meat Grading and Certification (MGC) Branch, Quality System Certification Program (QSCP), provides voluntary conformity assessment and accreditation services under ISO Guide 65 to organic certification bodies to facilitate the marketing and distribution of certified organic agricultural products. The MGC Branch is an independent third party, and strives to provide services in accordance with accepted industry practices and internationally recognized guidelines. All services are provided on a cost-recovery basis with fees as nearly equal as possible to the actual cost of providing the service.

### **Availability of Service**

MGC Branch Guide 65 accreditation services are available to U.S. organic certification bodies and international product certification bodies operating in the United States that certify organic agricultural products or systems that produce, process, or distribute agricultural products. The scope of accreditation for international certification bodies is limited to certification of products produced in the United States. International certification bodies may not include products produced outside the United States within the scope of their AMS Guide 65 accreditation.

### **Authority for Providing Service**

MGC Branch accreditation services are provided under the authority of the Agricultural Marketing Act of 1946, as amended, and the Code of Federal Regulations (CFR) 7, Part 37.

### **Nondiscrimination**

All MGC Branch services are provided without bias toward race, color, religion, age, gender, national origin, sexual orientation, and marital or familial status. Services are available without regard to membership in any organization, and are not contingent upon the number of certificates issued.

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"The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, and marital or family status. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at 202-720-2600 (VOICE or TDD). To file a complaint of discrimination, write USDA, Director, Office of Civil Rights, Room 326-W, Whitten Building, 14th and Independence Avenue, SW., Washington, DC 20250-9410 or call 202-720-5964 (voice or TDD). USDA is an equal opportunity provider and employer."

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## **Application for Service**

Persons interested in conformity assessment and accreditation services to ISO Guide 65 may contact the Washington Office (WO) in Washington, DC, on (202) 720-1113. The WO staff will provide a copy of ARC Instruction 1012, ISO Guide 65 Accreditation for Organic Certification Bodies; CFR 7, Part 37; and a copy of Form LS-314, Application for Auditing Services. Applicants may complete the Form LS-314 as described on the form and submit it to the WO along with the following:

1. A letter requesting user-fee conformity assessment services.
2. A complete quality manual as described in ISO Guide 65, section 4.5.3.
3. A current list of all clients certified by the applicant to be covered under the scope of the assessment, including locations and products certified.
4. Samples of brochures, advertisements, or other publicly available documents describing the certification services offered.

Upon receiving the application, an MGC Branch representative will contact the applicant for additional information, and arrange to provide services requested. The Branch will prepare a summary of requested services and forward it to the applicant for concurrence. The details of the summary will include:

1. Estimated duration and cost of the document review.
2. Estimated duration of the initial compliance audit and number of locations to be reviewed.
3. Frequency and duration of surveillance audits and number of locations to be reviewed.
4. Estimated travel and per diem expenses associated with the audits.
5. Total estimated annual costs of providing service.

## **Assessments**

Certification program assessments are conducted in accordance with ISO 10011-1:1990, Guidelines for auditing quality systems-Part 1-Auditing.

Document reviews. A qualified auditor will evaluate initial applications and quality manuals with the assistance of organic industry subject matter experts, as necessary. The initial document review will include a detailed analysis of all program requirements according to ISO Guide 65.

Upon successful completion of the initial document review, the manager will assign the lead auditor who will be responsible for the onsite compliance audits.

Compliance audits. Qualified lead auditors employed by the MGC Branch will conduct a detailed audit of certification program activities at the applicant's place of business. The purpose of the onsite audit is to validate policies and procedures described in the applicant's quality manual. Onsite audits will be of sufficient duration and detail to provide auditors with reasonable assurance that the policies and

procedures stated in the applicant's quality manual have been fully implemented and achieve the desired program objectives. Compliance audits will include a review of inspection activities at one or more producers and one or more processors under contract with the certifier. At the conclusion of the audit, the lead auditor will discuss the audit findings at a closing meeting and forward the findings to the Program Review and Approval Committee for final disposition.

### **Auditors**

Auditors assigned to provide onsite evaluations must be qualified as MGC Branch lead auditors as described in MGC Instruction 304, Training and Experience Requirements for Quality System Auditors. Auditors must have signed conflict of interest statements and appropriate disclosure agreements on file with the Branch prior to assignment to provide service to a specific applicant.

### **Program Review and Approval Committee**

An LS Program Review and Approval Committee will be appointed by the QSCP manager, and will consist of two or three representatives. The committee will consist of two representatives from the MGC Branch, the Standardization Branch, or the Program Review and Resource Management Staff plus a subject matter expert from the National Organic Program.

### **Decisions on Accreditation**

All decisions on accreditation will be based on recommendations of the LS Program Review and Approval Committee to the QSCP manager, who issues the final approval.

Basis for evaluation. The Program Review and Approval Committee will review programs as assigned and base their recommendations on the following criteria. To recommend approval, committee members must find that programs:

1. Appropriately address all elements of ISO Guide 65.
2. Clearly define the scope of the certification services provided.
3. Have demonstrated an effective and credible certification program.
4. Have necessary financial resources to pay for QSCP services.

Granting accreditation. The QSCP manager may grant accreditation to applicants upon successful completion of the document review, compliance audit, and by recommendation of the Program Review and Approval Committee.

Denying accreditation. Committee members may elect to deny initial accreditation to an applicant for any of the following reasons:

1. Failure by an applicant to submit documentation that demonstrates compliance with all provisions of ISO Guide 65.
2. Failure to provide objective evidence of complete program implementation during the course of the initial onsite compliance audit.

3. Failure to submit the necessary fees.
4. Failure to provide unlimited access to applicants' records within the scope of the accreditation when requested by LS Program officials.
5. Presenting false or misleading information to any LS Program official at any point in the accreditation process.

Duration of accreditation. Certificates of accreditation are valid for 1 year, at which time applicants may request renewal.

Maintaining accreditation. Applicants are required to maintain program documentation and systems as described in their quality manuals. Accredited programs must be reviewed by AMS auditors at least annually to ensure continuing compliance with approved program documentation.

### **Amendments to Scope of Accreditation**

Any changes to the scope of the accreditation must be submitted in writing to the QSCP manager for review by the Committee at least 30 days prior to the proposed effective date of the changes. Requests for amendments must include a clear description of the proposed changes. Substantive changes may require additional document and onsite compliance audits as determined by the QSCP manager.

### **Suspending Accreditation**

Suspension. The QSCP manager may temporarily suspend accreditation of programs for any of the following reasons:

1. Failure by the accredited program to take required corrective/preventive action to a previously documented nonconformance.
2. Implementing substantive changes in the accredited program without prior written approval.
3. Misuse or misrepresentation of official certificates or accreditation status and failure to take effective corrective/preventive action within 30 days of notification.
4. Failure to pay QSCP fees within 60 days of original billing date.

Notification of suspension. The QSCP manager will arrange to notify the applicant in writing of any decision to suspend accreditation within 5 working days of the Committee's recommendation. Notification will include details of nonconformances, conditions for reinstatement of accreditation, and timeframes for completion.

### **Withdrawal of Accreditation**

Withdrawal. The Branch may withdraw accreditation of a certification body for any of the following reasons:

1. Repeated failure to maintain system in compliance with referenced standards and approved procedures.
2. Failure of suspended programs to meet conditions for reinstatement within required timeframes.

Removal from lists of accredited certification bodies. Certification bodies that have had their accreditation suspended or withdrawn will have their names and program information removed from all official lists of accredited programs in accordance with **Publication of Accreditation Status**.

Surrender of certificates. Withdrawal of accreditation will result in cancellation and recall of the applicant's certificate of compliance. Applicants must surrender certificates of compliance or file a written appeal within 10 working days of written request of the QSCP manager.

If certificates are cancelled, applicants must immediately discontinue use, reference to, or distribution of materials that make reference to USDA Guide 65 accreditation. Applicants must effectively recall or arrange for discontinuation of distribution all point-of-purchase materials referencing or implying conformity assessment by AMS within 10 working days of written notification by AMS.

If applicants fail to surrender certificates or discontinue use of marks of conformity as required by this instruction, AMS may issue a press release stating the discontinued eligibility of the applicant to reference AMS accreditation and the reasons for certificate withdrawal.

## **Appeals**

Applicants have the right to appeal the findings of any audit or decisions based on those findings. Appeals regarding an applicant's accreditation or any audit findings must be submitted in writing to the MGC Branch Chief within 10 days of the date of the official report rendering the findings or decisions. Requests for appeal must include:

1. The basis for the appeal.
2. The requested alternative decision or actions.

The MGC Branch Chief will review the request, and contact the applicant of the final disposition of the appeal within 30 working days of receipt of the request.

## **Insurance**

All applicants are required to maintain appropriate insurance for liabilities associated with their certification activities. Programs requesting accreditation must provide documents demonstrating insurance coverage or show evidence of self-insurance. The QSCP manager will maintain a copy of the documentation in the applicant's file in the WO. Applicants must notify the manager of any changes to the coverage, and provide copies of the revised policy coverage prior to the effective date of the change.

## **Fees for Service**

LS Program employees will provide auditing services in the most efficient, cost-effective manner possible with consideration to the needs of the applicant, the capabilities and needs of the Program, and sound management practices.

When assigning auditors to perform specific audits, the QSCP manager will give consideration to providing service using the auditor who would incur the least travel cost. However, auditor assignments will also include considerations such as ensuring uniformity of service, specialized training, personnel staffing issues, and specific program needs. It will be the responsibility of the QSCP manager to staff audits in the most cost-effective manner possible while ensuring uniform, high-quality service.

Fee rate. Fees charged for service will be charged according to the approved hourly rate published in the Federal Register. Hourly fees will be assessed for official time required to prepare for, conduct, and report the results of assessments and time required to complete all related travel.

Audit preparation. Applicants will be billed for official time required to prepare for quality system audits performed on their behalf. Official preparation time will include review of approved quality manuals, records from previous audits, and preparation of checklists. The amount of preparation time necessary to prepare for an audit will depend upon the complexity of the system to be audited, the volume of documentation, and the number of nonconformances and corrective actions from previous audits.

Travel. Applicants will be charged for travel time to and from the assigned auditors' official duty location and between audit sites. When traveling to provide service to multiple applicants, charges will be prorated between the applicants.

Recording hours charged. Hours of service to be charged to the applicant will be documented on LS Form 5-3 (1-93), Agricultural Products Certificate and submitted to the MGC Branch Office of Field Operations, Denver, Colorado, for billing. Copies of the charge certificate will be maintained with the audit working papers.

## **Certificates of Compliance**

Upon recommendation of the Review and Approval Committee, the QSCP manager will issue an official certificate of compliance to ISO Guide 65, stating the location and scope of the program evaluated, the standards assessed, and the effective dates of the certificate. Certificates will be valid for up to 1 year and may be renewed provided systems are maintained as described in program documentation and subsequent audits provide objective evidence of ongoing compliance.

## **References to Official Certification**

Text references. Organic certification bodies who hold valid certificates of compliance may make references to AMS accreditation in company brochures, advertisements, and official documents, provided remarks or references are complete and not misleading. Acceptable references may include, for example, "[Name of certifier] organic product certifications are accredited under ISO Guide 65 by the U.S. Department of Agriculture."

Official marks, shields, stamps, and logos. No official USDA shields, stamps, logos, or other marks may be used by organic certification bodies or their clients on certified products, correspondence, advertising, or promotional material unless products have been officially graded or certified by an AMS employee using official U.S. product standards or specifications.

## **Publication of Accreditation Status**

Upon successful completion of the assessment process, the QSCP manager will arrange to post the applicant's accreditation status on the LS Program's Internet web site. The posting will include the terms, scope, and limitations of the accreditation. The QSCP manager may also post information regarding applications in various stages of approval when it is reasonable to expect that the applicant will successfully complete the accreditation process within a reasonable time period.

Removal from lists of accredited programs. A program whose accreditation has expired or has been suspended or withdrawn will immediately be removed from all official lists of accredited programs. The QSCP manager will arrange to notify all bodies that have agreed to base further certifications or access to other marketing programs based on LS Program accreditation of the action.

### **Confidentiality**

Conformity assessment and accreditation services are designed to provide confidence in the ability of the certification body to provide credible product certification services. All quality manuals submitted by applicants and maintained by the LS Program are available for public inspection and are subject to complete disclosure under the Freedom of Information Act. Any portion of the program documentation that the applicant considers proprietary must be identified to the committee at the time the information is submitted along with written justification why said documents should not be released to or reviewed by the public.

If, upon review of the information, the Review and Approval Committee agrees that the identified information is indeed proprietary and that protecting the information from public review will not hinder public confidence in the system, the manager will make appropriate provisions to protect the information from disclosure to the extent possible under existing Federal laws.

*/s/ Larry R. Meadows*

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